

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

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CONTAINS CONFIDENTIAL DUSINESS INFORMATION

DP BARCODE No.: D429387

FILE SYMBOL NO.: 91601-R

DECISION No.: 508305

PC CODES: 081800,081700

COMPANY NAME: Senes Tech, Incorporated

FOOD USE: No

ACTION CODE: R 110x2

PRODUCT NAME: ContraPest

DATE OUT:

July 21, 2016

SUBJECT

End-Use Product Chemistry Review

Product Name: ContraPest

FROM:

Bruce F. Kitchens, Chemist Product Chemistry Team

Chemistry, Inerts and Toxicology Assessment Branch/RD (7505P)

TO:

RM# 07, Mark Suarez/Jacquelyn Marchese

Invertebrate and Vertebrate Branch3

Registration Division (7505P)

INTRODUCTION:

The registrant, Senes Tech, Incorporated, is submitting an application to register the proposed end-use product, ContraPest. This product is a restricted use pesticide. The active ingredients in this product are Triptolide and 4-Vinylcyclohexene diepoxide (VCD) at label nominal concentrations of 0.00118 and 0.09604% a.i., respectively. Both active ingredients are unregistered. This product is intended for use as a rat contraceptive. In support of this request, the registrant is submitting a proposed basic CSF (Confidential Statement of Formula) dated 31 Mar 2016; a draft label and product chemistry data contained in MRID#s 497001-18, 497001-18 and 497001-19. During the course of this review, the registrant submitted additional data contained in MRID#s 498934-01 and 499088-01 for clarification of the product's stability and the certified limits. A revised basic CSF dated 28 Apr 2016 was also submitted. The Chemistry, Inerts and Toxicology Assessment Branch (CITAB) has been asked to review this submission.

SUMMARY OF FINDINGS:

1. Name of Active Ingredients:

Triptolide (0.00118% a.i.) VCD (0.09604% a.i.)

2. Has the registrant claimed substantial similarity to a registered product?

[] Yes; [X] No; [] NA; if yes give the registration number of the cited product.

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3. All of the source materials of	the active ingredient are derive	ed from registered sources-[] Yes [X] No
The sources of the active ingred will be evaluated in separate sul		redient are derived from registered sources- [] Yes [X] No registered. Product chemistry data for each unregistered source 29316 & D429386). IIAB and are approved for the proposed labeled uses. Resubmitted Dated: 28 Apr 2016 Resubmitted Dated: 33 tration of Al listed on CSF concurs with product label ingredient nominal concentration. PR Notice 97-6 (inert ingredient vs other ingredient) IA I
All inert ingredients have bee [X] Yes [] No	n screened by IIAB and are ap	proved for the proposed labeled uses.
5. Confidential Statement of Fo	rmula:	
[X] Basic - Dated: 31 Ma [] Alternate - Dated:		
Alternate CSF complies with [] Yes [] No [X] NA	40 CFR 152.43	
6. Product label		
a. Ingredient statement: No (PR Notice 91-2). [X] Yes [] No, if not,		d on CSF concurs with product label
Label is being revised to	correct active ingredient nomin	nal concentration.
Is the sub statement in c [X] Yes; [] No; if not, exp		(inert ingredient vs other ingredient)
Metallic equivalent: Soluble arsenic: Isomeric ratios: Acid Equivalent:	[] Yes [X] NA [] Yes [X] NA [] Yes [X] NA [] Yes [X] NA	
b. Health related sub state	ments: Product contains?	
Methanol at > 4	%: [] Yes; [] No	p; [X] NA
	rd statement: Product label re tential or electric insulator brea	
Is the sub statement in c		(Total Release Fogger)?
d. Label requires an addi	tional Storage and Disposal st	atement: [] Yes [X] No: if yes explain below

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7. Group A: Product Chemistry Data

CITAB's determination of the acceptability for the proposed product is listed in the tables below.

Guideline No.	Study Title		Data submitted		CITAB's Assessment	MRID Nos.
			Yes	No	of Data	
830.1550	Product Identity & Composition		X		Α	497001-16
830.1600	Description of materials used to produce the product		x		A	497001-16
830.1650	Description of formulation process		x		A	497001-16
830.1670	Discussion on the formation of impurities		x		А	497001-16
830.1700	Preliminary analysis		X		A	497001-17
830.1750	Certified limits (158.350)	Standard certified limits	х		A	see csf 4/28/16
		Proposed Limits				
		Justification for wider limits				
830.1800	Enforcement analytical method		×		A	497001-18

A = Acceptance, N = Not Acceptable, G = Data Gap, W = Waiver Request, I = In Progress, NA = Not Applicable; U = Upgradeable.

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8. Group B:

FOOD USE: No

Guideline No.	Study Title	Value or Qualitative Description	CITAB's Assessment of Data	MRID Nos.
830.6303	Physical State	Product is an opaque, white liquid with a sweet, milky aroma.	A	497001-19
830.6314	Oxidation/ Reduction	Product does not contain oxidizing or reducing agents.	N/A	497001-19
830.6315	Flammability	Product does not contain flammable components.	N/A	497001-19
830.6316	Explodability	Product does not contain explosive components.	N/A	497001-19
830.6317	Storage stability	Cited observations submitted. A controlled study not conducted.	G	497001-19
830.6319	Miscibility	Product not an EC nor diluted with petroleum solvents.	N/A	
830.6320	Corrosion Characteristics	Cited observations submitted. A controlled study not conducted.	G	497001-19
830.7000	рН	7.26	А	497001-19
830.7100	Viscosity	0.944 cp	A	497001-19
830.7300	Density (units)	0.971 kg/L (0.971 g/ml)	А	497001-19

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